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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,262	04/17/2002	Bruno Criere	017751-030	8894

21839 7590 04/01/2005

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/030,262	Applicant(s) CRIERE ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 March 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 18 March 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-7 and 9-46.
Claim(s) withdrawn from consideration: _____.


AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.

Continuation of 13. Other: the newly presented claims 21-46 are also rejected over the prior art of record for the reasons mentioned in the previous action. In particular, the new claims do not recite any specific percentage of fenofibrate unlike the previously claimed "greater than or equal to 60% by weight" and hence falls within the range of fenofibrate taught by Stamm et al. The limitation of mass ratio of fenofibrate to cellulose derivative (also presented in the previous claims) in the new claims would have been obvious for the same reasons as mentioned before. Applicants argue that neither Stamm nor Deboeck teach or suggest the claimed composition with greater than 60% by weight of micronized fenofibrate and 2 to 15% by weight a binding cellulose derivative. Applicants argue that the claimed invention is not obtained by mere optimization because the prior art does not encompass the invention. Applicants arguments are not persuasive because Stamm teaches the same active agent and same polymers and hence encompasses the invention. As applicants themselves state the instant subject matter is not patentable absence evidence of criticality of the percentages. Applicants have not established the criticality of the claimed high amount of active agent and low amounts of polymers and the references nowhere teaches away from employing the claimed ranges or percentages of fenofibrate and polymers. In this regard, it is examiner's position that Stamm et al does recognize the parameters i.e, amounts of fenofibrate and polymers and mere variation in the percentages requires only routine optimization. With respect to Deboeck, applicants admit that the reference teaches 5 to 95% fenofibrate and yet argues that the preferred range is 45 to 55%. However, the prior art teachings are not limited to preferred embodiments and should be taken as a whole. Thus, manipulating the amounts of fenofibrate (from the teachings of Stamm or Deboeck) to achieve a desired activity would have within the scope of a skilled artisan. With respect to the polyglycolized glycerides (of Deboeck) instant claim language allows for additional ingredients of prior art. Therefore, the rejection has been maintained.


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